

IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: C. R. BARD, INC.,  
PELVIC REPAIR SYSTEM  
PRODUCTS LIABILITY LITIGATION

MDL No. 2187

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THIS DOCUMENT RELATES TO C. R. BARD WAVE 4 & WAVE 5 CASES

MEMORANDUM OPINION AND ORDER  
(*Daubert* Motion re: Bernd Klosterhalfen, M.D.)

Pending in *In re C. R. Bard, Inc. 2:10-md-2187*, MDL 2187, is C. R. Bard, Inc. (“Bard”)’s *Daubert* motion<sup>1</sup> to Exclude Opinions and Testimony of Bernd Klosterhalfen, M.D. [ECF No. 4572]. The motion is now ripe for consideration because the briefing is complete. As set forth below, Bard’s motion is **GRANTED in part** and **DENIED in part**.

**I. Background**

These groups of cases reside in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation (“MDL”) concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse (“POP”) and stress urinary incontinence (“SUI”). In the seven MDLs, there are more than 29,000 cases currently pending, approximately 3,000 of which are in the C. R. Bard, Inc. MDL, MDL No. 2187.

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<sup>1</sup> Rather than refile, Bard entered a “notice” adopting prior *Daubert* motions that incorporate the parties positions previously formulated in Waves 1 and 2.

In an effort to manage the massive Bard MDL efficiently and effectively, the court decided to conduct pretrial discovery and motions practice on an individualized basis. To this end, I selected certain cases to become part of a “wave” of cases to be prepared for trial and, if necessary, remanded.

Upon the creation of a wave, I enter a docket control order subjecting each active case in the wave to the same scheduling deadlines, rules regarding motion practice, and limitations on discovery. *See, e.g.*, Pretrial Order (“PTO”) # 236, *In re C. R. Bard, Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, No. 2:10-md-02187, Jan. 27, 2017, <https://www.wvsc.uscourts.gov/MDL/2187/orders.html>. Included among the discovery rules imposed by the court is the obligation of the parties to file *Daubert* motions seeking to limit or exclude the testimony of general experts in the main MDL, MDL 2187, and to identify which cases the motion would affect.

## **II. Legal Standard**

Under Federal Rule of Evidence 702, expert testimony is admissible if it will “help the trier of fact to understand the evidence or to determine a fact in issue” and (1) is “based upon sufficient facts or data” and (2) is “the product of reliable principles and methods” which (3) has been reliably applied “to the facts of the case.” Fed. R. Evid. 702. A two-part test governs the admissibility of expert testimony. The evidence is admitted if it “rests on a reliable foundation and is relevant.” *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579, 597 (1993). The proponent of expert testimony does not have the burden to “prove” anything. However, he or she must “come forward with

evidence from which the court can determine that the proffered testimony is properly admissible.” *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998).

The district court is the gatekeeper. It is an important role: “[E]xpert witnesses have the potential to be both powerful and quite misleading”; the court must “ensure that any and all scientific testimony . . . is not only relevant, but reliable.” *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (citing *Daubert*, 509 U.S. at 588, 595; *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999)). I “need not determine that the proffered expert testimony is irrefutable or certainly correct” – “[a]s with all other admissible evidence, expert testimony is subject to testing by ‘[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.’” *United States v. Moreland*, 437 F.3d 424, 431 (4th Cir. 2006) (alteration in original) (quoting *Daubert*, 509 U.S. at 596 (alteration in original)); *see also Md. Cas. Co.*, 137 F.3d at 783 (“All *Daubert* demands is that the trial judge make a ‘preliminary assessment’ of whether the proffered testimony is both reliable . . . and helpful.”).

*Daubert* mentions specific factors to guide the overall relevance and reliability determinations that apply to all expert evidence. They include (1) whether the particular scientific theory “can be (and has been) tested”; (2) whether the theory “has been subjected to peer review and publication”; (3) the “known or potential rate of error”; (4) the “existence and maintenance of standards controlling the technique’s operation”; and (5) whether the technique has achieved “general acceptance” in the

relevant scientific or expert community. *United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003) (quoting *Daubert*, 509 U.S. at 593-94).

Despite these factors, “[t]he inquiry to be undertaken by the district court is ‘a flexible one’ focusing on the ‘principles and methodology’ employed by the expert, not on the conclusions reached.” *Westberry*, 178 F.3d at 261 (quoting *Daubert*, 509 U.S. at 594-95); *see also Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999) (“We agree with the Solicitor General that ‘[t]he factors identified in *Daubert* may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert’s particular expertise, and the subject of his testimony.’” (citation omitted)); *see also Crisp*, 324 F.3d at 266 (noting “that testing of reliability should be flexible and that *Daubert*’s five factors neither necessarily nor exclusively apply to every expert”).

With respect to relevancy, *Daubert* also explains:

Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful. The consideration has been aptly described by Judge Becker as one of “fit.” “Fit” is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes. . . . Rule 702’s “helpfulness” standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.

*Daubert*, 509 U.S. at 591-92 (citations and internal quotation marks omitted).

### III. Analysis

Bard seeks to exclude certain opinions of Dr. Bernd Klosterhalfen. Dr. Klosterhalfen is a pathologist who has “personal experience with synthesizing, characterizing and processing a wide variety of polymeric materials.” Notice by Pls.

of Adoption of Prior Daubert Resp. to Notice of Adoption of Mot. to Exclude the Ops. & Test. of Bernd Klosterhalfen, M.D. in Wave 4 & Wave 5 Cases, Ex. 8 (Klosterhalfen Report) at 5 [ECF No. 4595–4]. Bard moves to exclude the following opinions offered by Dr. Klosterhalfen: (1) surface degradation of polypropylene; (2) Bard’s state of mind; (3) opinions based on personal data pools; and (4) opinions not offered in Rule 26(f) report. This is not the first time I have reviewed *Daubert* challenges to Dr. Klosterhalfen’s opinions on these topics, and my findings today remain largely consistent with past decisions.

#### 1. Surface Degradation

First, Bard argues that Dr. Klosterhalfen’s opinions with regard to polypropylene degradation do not fit the facts of the case because he has not seen any degradation on the plaintiffs’ explants. Dr. Klosterhalfen relies on sufficient and reliable bases in forming his opinion that polypropylene degrades and the effects of such degradation *generally*. However, there does not appear to be any connection between his surface degradation opinions and the plaintiffs’ specifically. *See* Ex. C (Bard’s Mem. of Law in Supp. of Mot. to Exclude the Ops. of Bernd Klosterhalfen, M.D.) at 3 (citing deposition testimony where Dr. Klosterhalfen stated he had not seen surface degradation on any of the eleven explants he reviewed) [Docket 4572-3]. Therefore, I **FIND** that Dr. Klosterhalfen’s opinions are limited to polypropylene degradation and the effects of such degradation generally.

#### 2. State of Mind

Next, Bard contends that Dr. Klosterhalfen should not be permitted to opine as to Bard's state of mind. The plaintiffs appear to partially concede that Dr. Klosterhalfen will not offer opinions as to Bard's state of mind. Regardless, I have repeatedly held that a party's knowledge and state of mind are not appropriate subjects of expert testimony because opinions on these matters will not assist the jury. Accordingly, Bard's motion with regard to state of mind is **GRANTED**, and these opinions are **EXCLUDED**.

### 3. Data Pools

Next, Bard argues that Dr. Klosterhalfen should be precluded from relying on his personal database because it has not been produced and is unreliable. In response, the plaintiffs contend that, consistent with this court's previous findings, Dr. Klosterhalfen's reliance on his personal database is part of his knowledge and experience. In *In re C.R. Bard, Inc.*, I allowed Dr. Klosterhalfen to rely on his personal database in forming his expert opinions. *See* 948 F .Supp. 2d 589, 622 (S.D. W. Va. 2013). However, I also noted that Bard failed to timely move to compel the production of the explant database. *Id.* Here, Bard timely moved to compel. *See* Mot. to Compel [ECF No. 1355]. Thereafter, I denied Bard's motion to compel, agreeing with Magistrate Judge Eifert's recommendation that granting Bard's request would quickly devolve into a mini-trial on Dr. Klosterhalfen. *See* Pretrial Order # 172 [ECF No. 1517]. Through Bard's Motion to Compel, this issue has developed, and I now **FIND** that without a fully synthesized representation of Dr. Klosterhalfen's database, specific reliance on that database is unreliable.

Accordingly, Bard's motion with regard to Dr. Klosterhalfen's personal database is **GRANTED**, and these opinions are **EXCLUDED**.

4. Opinions Not in Rule 26(f) Report

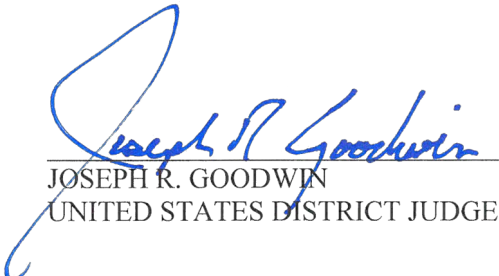
Last, Bard contends that Dr. Klosterhalfen should be precluded from offering opinions that are not in his Rule 26(f) report, as well as opinions he agreed not to offer during his deposition. The plaintiffs concede that Dr. Klosterhalfen will not offer opinions on subjects for which he testified that he is not an expert. Accordingly, Bard's motion with regard to these opinions is **DENIED as moot**.

**IV. Conclusion**

To summarize, I **GRANT in part, DENY in part, and DENY as moot** Bard's motion concerning Bernd Klosterhalfen, M.D. [ECF No. 4572] consistent with my reasoning above.

The court **DIRECTS** the Clerk to file a copy of this Memorandum Opinion and Order in 2:12-md-2187, and the Bard Wave 4 and Wave 5 cases identified in the Exhibit attached hereto. The court further **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: January 23, 2018

  
JOSEPH R. GOODWIN  
UNITED STATES DISTRICT JUDGE

# **EXHIBIT A**



PLAINTIFF	CURRENT CIVIL ACTION #	WAVE
Barker, Lorie	2:13-cv-33690	4
Bivens, Geraldine L	2:16-cv-11116	4
Black, Brenda L	2:14-cv-00952	4
Branscome, Christine E	2:16-cv-10995	4
Brewer, Pamela R	2:16-cv-11135	4
Brown, Cathy	2:16-cv-10807	4
Carnahan, Kathy	2:13-cv-24208	4
Cooley, Dedra	2:14-cv-07543	4
Cuffee, Carolyn D	2:14-cv-02528	4
Degarmo, Nora	2:12-cv-07578	4
Drake, Theresa	2:16-cv-03709	4
Edwards, Claudine	2:14-cv-27463	4
Ford, Janet Marie	2:14-cv-09878	4
Gardiner, Gloria	2:13-cv-15209	4
Gilbert, April D	2:16-cv-11118	4
Gritten, Linda	2:16-cv-03707	4
Guerrero, Angelia	2:14-cv-14209	4
Hall, Cardisa M	2:16-cv-11113	4
Henderson, Teresa	2:16-cv-03779	4
Holmes, Robin	2:13-cv-01524	4
Hummel, Niki	2:13-cv-32359	4
Johnson, Nancy	2:13-cv-19736	4
Jones, Thelma J	2:16-cv-03719	4
Keisling, Linda	2:16-cv-03721	4
Lackey, Danielle R	2:16-cv-11011	4
Landers, Samantha	2:13-cv-26574	4
Ledwein, Judy	2:16-cv-03778	4
Lee, Frankie	2:12-cv-07570	4
Long, Pamela D	2:13-cv-20881	4
Martin, Judy A	2:16-cv-11103	4
Massey, Shannon L.	2:14-cv-01027	4
McWilliams, Brenda K	2:16-cv-11104	4
Miller, Alice F	2:16-cv-11014	4
Moore, Carol	2:16-cv-03842	4
Moore, Carolyn S	2:14-cv-00606	4
Morgan, Khristina S	2:16-cv-11016	4
Nadeau, Susan J	2:16-cv-11112	4
Nall, Stephanie	2:13-cv-01526	4
Newell, Carmen	2:13-cv-16405	4
Phelps, Inna V	2:16-cv-11114	4
Pickering, Hope	2:16-cv-03896	4
Politi-Topal, Kathleen D.	2:14-cv-01411	4
Powell, Mary C	2:16-cv-11017	4

PLAINTIFF	CURRENT CIVIL ACTION #	WAVE
Powers, Lisa R	2:16-cv-11041	4
Priddy, Judy M	2:13-cv-10318	4
Purcell, Kim	2:13-cv-34058	4
Radatz, Mary L.	2:13-cv-17989	4
Raines, Cynthia Ann	2:13-cv-26748	4
Richardson, Cynthia O	2:13-cv-20036	4
Richardson, Demetria	2:12-cv-02564	4
Rodericks, Rhonda K	2:16-cv-11115	4
Rogers, Rosemary J	2:16-cv-11106	4
Sheaffer, Julie A	2:14-cv-05601	4
Silvia, Diane	2:14-cv-25366	4
Smith, Tamela	2:13-cv-30640	4
Speetzen, Michelle	2:13-cv-12416	4
Stapel, Catherine	2:14-cv-25362	4
Stewart, Mary Sue	2:14-cv-27466	4
Stoddard, Sloane	2:14-cv-11940	4
Struble, Maureen	2:16-cv-03817	4
Swiney, Ernestine F	2:16-cv-11021	4
Teeples, Mistie D	2:16-cv-11020	4
Toulson, Patricia	2:16-cv-03816	4
Updike, Melody A	2:16-cv-11035	4
Weber, Erika	2:16-cv-11105	4
Wilson, Elizabeth J	2:14-cv-14119	4
Woodard, Elizabeth E	2:16-cv-11040	4
Alvey, Christine	2:16-cv-07705	5
Bailey, Carla	2:16-cv-06362	5
Barton, Joan	2:16-cv-07655	5
Bess, Joyce	2:16-cv-06318	5
Clarke, Janice	2:16-cv-10809	5
Cole, Jeanene	2:16-cv-07402	5
Collins, Dana	2:16-cv-06739	5
Corley-Davis, Celia	2:16-cv-10811	5
Crook, Julie	2:16-cv-06360	5
Crowe, Karen F	2:16-cv-11136	5
Currie, Arlene	2:16-cv-10814	5
Daily, Catherine T	2:16-cv-11137	5
Davis, Debra M	2:16-cv-11139	5
Dennis, Barbet	2:16-cv-10815	5
Donley, Teresa	2:16-cv-07322	5
Donovan, Thoris L	2:16-cv-11142	5
<del>Duncan, Andrea</del>	<del>2:16-cv-10816</del>	5
Ellis, Karen	2:16-cv-07694	5
Elrod, Josephine	2:16-cv-04032	5

PLAINTIFF	CURRENT CIVIL ACTION #	WAVE
Fay, Paula A	2:16-cv-11144	5
Frederick, Cheryl D	2:16-cv-11266	5
Hale-Cuellar, Patricia A	2:16-cv-11150	5
Hauber, Elizabeth A	2:16-cv-11158	5
Herrera, Wynde Lynn	2:16-cv-10819	5
Hill, Mignon M	2:16-cv-11161	5
Jasso, Mary	2:16-cv-06361	5
Jeffries, Lynda	2:16-cv-11798	5
Johnson, Elisa J	2:16-cv-11147	5
Josey, Tammy	2:16-cv-11803	5
Knernschiold, Peggy	2:16-cv-06743	5
Kolodzyk, Virginia L	2:16-cv-11163	5
Krishnan, Meera	2:16-cv-06740	5
Kyes, Marilyn	2:16-cv-11804	5
Leyba, Lorraine	2:13-cv-16401	5
Lingenfelter, Nancy	2:16-cv-07610	5
Mahnke, Joyce C	2:16-cv-11167	5
Martinez, Tammy	2:16-cv-10821	5
Mathis, Nellie	2:16-cv-08014	5
Miecznikowski, Jennifer C	2:16-cv-11169	5
Morrill, June	2:16-cv-11170	5
Nichols, Brandey R	2:16-cv-11186	5
Piper, Connie	2:16-cv-11811	5
Prince, Marjorie	2:16-cv-04949	5
Reynolds, Cassandra	2:16-cv-11175	5
Roberts, Carla	2:16-cv-06741	5
Roberts, Sheila	2:16-cv-05003	5
Smith, Sandra	2:16-cv-11817	5
Stephenson, Erin	2:16-cv-11819	5
Stevens, Terri L	2:16-cv-11820	5
Tatum, Tuesday	2:16-cv-11821	5
Thompson, Reba	2:16-cv-04536	5
Watson, Charlotte	2:16-cv-03989	5
Yoder-Brady, Bobbye	2:16-cv-03954	5
Young, Carolyn	2:16-cv-04037	5